DEC 2 7 2010 K102572

SAINATH INTELLECTUAL PROPERTIES, LLC

FOI RELEASABLE

1. Submitter:

SaiNath Intellectual Properties, LLC
9438 Pebble Beach Ct. West
Seminole, FL 33777
Telephone: 813-222-1190
Fax: 813-229-8313

Contact: Christopher Paradies
Date Prepared: August 27, 2010

2. Device:

Trade Name: IYUNNI™ 3ID Suprapubic Cystostomy Tube Kit
Classification Name: 78 KOB Suprapubic Catheter & Accessories
Regulation Number: 876.5980
Product Code: KOB
Classification: Class II

3. Predicate Device:

IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit, K092049
Rüsch Suprapubic Catheter Tray/Kit, K970021
Rüsch Supraflex™ Suprapubic Catheter, K952187

4. Device Description:

The kit consists of two major components: IYUNNI™ Suprapubic Cystostomy Tube and IYUNNI™ Soft Collar Introducer Dilator. The kit is used for percutaneous bladder drainage.

5. Intended Use:

The kit is used for percutaneous bladder drainage and to drain fluids to and from the urinary tract. The usage of this product is identical to previous devices, which have the same technological characteristics.

6. Technological Characteristics

The proposed IYUNNI™ 3ID Suprapubic Catheter kit is similar in design, materials, and manufacturing processes to the predicates IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit, K092049; Rüsch Supraflex™ Suprapubic Catheter Kit, K952187; and the Rüsch Suprapubic Tray/Kit, 970021.

7. Performance Data:

Testing has been performed and all components, subassemblies, and/or full devices met the requires specifications for the completed tests.

8. Conclusion:

SaiNath Intellectual Properties, LLC has demonstrated that the proposed IYUNNI™ 3ID Suprapubic Catheter Kit is substantially equivalent in intended use and indications to the predicate devices, IYUNNI™ 3ID Tri-Funnel Gastrostomy Tube Kit, K092049; Rüsch Supraflex™ Suprapubic Catheter Kit, K952187; and the Rüsch Suprapubic Tray/Kit, 970021. Technological differences have been qualified through biomaterial assessments and bench testing, the result of which did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

SaiNath Intellectual Properties LLC
c/o Christopher Paradies, Ph.D.
Fowler White Boggs P.A.
501 East Kennedy Blvd., Suite 1700
TAMPA FL 33602

DEC 27 2010

Re: K102572
Trade/Device Name: IYUNNI™ 31D Suprapubic Catheter Kit
Regulation Number: 21 CFR §876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: II
Product Code: KNT
Dated: December 6, 2010
Received: December 10, 2010

Dear Dr. Paradies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit/tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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SECTION 4\Page 4-1
INDICATIONS FOR USE

510(k) Number (if known): ~~To Be Determined~~ K102572

Device Name: IYUNNI™ Suprapubic Catheter Kit

Indications for Use:

The IYUNNI™ 3ID Suprapubic Cystostomy Kit is indicated for use in suprapubic bladder catherization and drainage of fluids to and from the urinary tract.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102572